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10/718,997	11/21/2003	Ning Wei	KCX-691 (18379)	9089

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,997	WEI ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's amendment to claim 14 is acknowledged.

Currently, claims 14 – 19 are pending and under examination. Claims 1 – 13 and 20 – 28 are acknowledged as withdrawn, as drawn to non-elected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14 – 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Boehringer et al. (US 2005/0170527).

Boehringer et al. teach a lateral flow (flow-through) assay device for detecting the presence or quantity of an analyte residing in a test sample, said lateral flow assay device comprising a porous membrane in communication with a labeled reagent (optical detection probes) conjugated with a specific binding member, such as a first antibody, specific for the analyte, said porous membrane defining:

a barrier (competitive) zone 16a that contains a second antibody immobilized on said porous membrane that is complexed to an antigen containing a label (optically

detectable substance), said antigen being identical to or an analog of the analyte and said label being capable of producing a signal when contained within said barrier zone; and

a detection zone 16b and 16c within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated labeled reagent to produce a first detection signal, said third antibody also being configured to bind to said antigen from said barrier zone to produce a second detection signal, wherein the amount of analyte within the test sample is determined from said detection signals (see Figure 1; and paragraphs [0054], [0057]-[0059], [0072], [0074], and [0090]).

With respect to Applicant's claims 15 and 16, the labels can comprise a visual label, such as a dyed latex bead, or a luminescent compound (see paragraph [0090]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (US 2005/0170527) in view of Polito et al. (US 2004/0018637).

The Boehringer et al. reference, which was discussed in the 102(e) rejection above, fails to teach that the labels used for the analyte and antigen (detection probes) emit signals at different wavelengths.

Polito et al. teach a method and apparatus for performing a lateral flow assay. The method utilizes detection agents in the form of particles to label an analyte(s) of interest in order to facilitate detection. Different detection agents can be used with different populations of analytes, wherein the different detection agents can comprise fluorescence agents that fluoresce at different wavelengths. The use of two different detection agents facilitates the detection of two different analytes of interest on the same test strip (see Abstract; and paragraphs [0036]-[0041]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Boehringer et al. the use of different labels for the antigen and analyte of interest, wherein the labels fluoresce at different wavelengths as taught by Polito et al. because Polito et al. teach the benefit of utilizing different detection reagents, such as fluorescence agents that fluoresce at different wavelengths, in order to detect two different analytes of interest, i.e. the analyte and antigen of Boehringer et al., on the same test strip.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (US 2005/0170527) in view of Harris et al. (US 2003/0162236).

Boehringer et al. also fail to teach the inclusion of a calibration zone that is configured to produced a calibration signal.

Harris et al. teach a method and test strip for measuring the amount of an analyte of interest in a fluid sample, wherein the test strip includes an application point, a contact region, a sample capture zone, and a control capture zone (calibration zone). The contact region contains analyte-binding particles, which bind to and label the analyte of interest. The sample and control capture zones contain immobilized capture reagents specific for the analyte or analyte-binding particles. When the fluid sample is contacted with the test strip, the fluid sample flows through the contact region, wherein any analyte in the sample can bind to the analyte-binding particles. The sample then flows to the sample and control capture zones, wherein a certain amount of analyte-binding particles bind to and are arrested in both the sample and control capture zones. The signals generated in both the sample and control capture zones are determined and compared in order to determine a ratio between 1) the amount of analyte-binding particles arrested in the sample capture zone, and 2) the amount of analyte-binding particles in the control capture zone. This ratio allows for an increased sensitivity and a more accurate determination of the amount of analyte of interest in a test sample, while also compensating for the variations that result from the dynamic nature of the assays (see paragraphs [0002]-[0007] and [0013]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Boehringer et al. a control/calibration zone as taught by Harris et al. because Harris et al. teach the benefit of including a control capture zone that generates a control signal with a test strip in order to determine a ratio that compares the signals generated in a sample capture zone (detection zone) and the control capture zone (calibration/control zone) in order to accurately determine the amount of analyte of interest in a test sample with increased sensitivity, while also compensating for the variations that result from the dynamic nature of the assays.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer et al. (US 2005/0170527) in view of Blatt et al. (US 2005/0196875).

Boehringer et al. fail to teach a specific formula for determining the amount of analyte within the test sample utilizing the signals generated in the various detection/barrier zones.

Blatt et al. teach an assay device for detecting an analyte within a test sample. The assay device can utilize two zones for binding to an analyte or particle-linked antibody (label) and providing a detectable signal in response to the bound components. The assay quantitation can be determined by reading the signals produced by the two zones, wherein the sample concentration is a result of a calibration algorithm related to the signals produced in the two zones, which provides for a more reliable quantitative analyte concentration result. Further, the summation of the

detectable signals from the two zones to produce a substantially constant total signal regardless of analyte concentration provides a reference mechanism for accurate assay performance (see Abstract; and paragraphs [0055]-[0057]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a formula or algorithm that utilizes the signals generated in the detection and/or barrier zones of Boehringer et al. as taught by Blatt et al. because Blatt et al. teach the benefit of creating an algorithm related to the signals produced by two zones contained on an assay device in order to quantitatively determine the concentration of an analyte in an applied test sample more reliably, wherein the summation of the detectable signals from the two zones can produce a substantially constant total signal regardless of analyte concentration, which provides a reference mechanism for accurate assay performance.

Response to Arguments

Applicant's arguments filed May 7, 2007 have been fully considered but they are not persuasive. Applicant argues (see p8) that none of the cited references, including the Boehringer et al. reference, teach that the amount of analyte within the test sample is determined using the signals created in the competitive zone, i.e. barrier zone of Boehringer et al., and the detection zone. However, this argument is not found persuasive.

Applicant's argument is drawn to a recitation of the intended use of the claimed invention, which must result in a structural difference between the claimed invention and

the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Boehringer et al. device contains all of the required limitations of Applicant's recited assay device, including the porous membrane in communication with a labeled reagent (optical detection probes) conjugated with a specific binding member, such as a first antibody, specific for the analyte, wherein said porous membrane includes:

a barrier (competitive) zone 16a that contains a second antibody immobilized on said porous membrane that is complexed to an antigen containing a label (optically detectable substance), said antigen being identical to or an analog of the analyte and said label being capable of producing a signal when contained within said barrier zone; and

a detection zone 16b and 16c within which a third antibody is immobilized that is configured to bind to complexes formed between the analyte and said conjugated labeled reagent to produce a first detection signal, said third antibody also being configured to bind to said antigen from said barrier zone to produce a second detection signal, wherein the amount of analyte within the test sample is determined from said detection signals (see Figure 1; and paragraphs [0054], [0057]-[0059], [0072], [0074], and [0090]).

Therefore, because the device of Boehringer et al. contains the structural limitations recited in Applicant's claimed device, the device of Boehringer et al. would produce the same signals in each of the zones, which could be used in the determination of the amount of analyte in the test sample. Thus, the device of

Boehringer et al. does anticipate Applicant's claimed invention because the device contains all of the required structural limitations and is therefore, capable of performing the intended use.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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